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re application of: **Richard Rosenbloom**

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Group Art Unit: **1617**

Filed: **May 2, 2001**

Examiner: **Mojdeh Bahar**

For: **COMPOSITIONS AND METHODS FOR THE TREATMENT
OF DIABETIC NEUROPATHY**

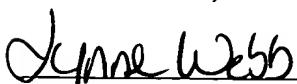
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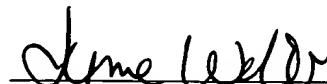
This is reply to the new issues raised in the Examiner's Answer dated June 4, 2003, in the above-identified application. Appellant respectfully submits that the sole remaining rejection in the Final Rejection should be reversed for the reasons given in the Appeal Brief and the additional reasons set forth below.

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I. First New Issue

In the Examiner's Answer, the Examiner, for the first time, took the position that,

...Riley teaches that it is best if Modules 1-3 are taken concomitantly. If one were to consider each module as a dosage form such as a tablet, following the teaching of Riley one would take the three tablets (Modules 1-3) concomitantly.

See page 4, section (11), part A of the Examiner's Answer. This argument fails for several reasons. First, a person taking Modules 1-3 of U.S. Patent no. 5,976,568 (Riley) does not arrive at the composition claimed in the claims of the present application since Modules 1-3 of Riley are each separate compositions.

Second, a person taking Modules 1-3 does not ingest the composition of the present invention since the amount of quercetin contained in Module 3 is not an amount effective to perform as an aldose reductase inhibitor in accordance with the requirements of the claims of the present application for the reasons given on pages 10-12 of the Appeal Brief. Note that the Examiner has repeated the erroneous statement at page 6 of the Examiner's Answer that the amount of quercetin in Module 3 is the same as the claimed amount. This statement is clearly incorrect as was explained on pages 10-12 of the Appellant's brief. The Examiner has not addressed the Appellant's reasoning found on pages 10-12 of the Appeal Brief and thus the conclusion should be drawn that the Appellant's reasoning is correct and that the Examiner is not correct in alleging that the amounts of quercetin are the same.

Third, the fact that Riley suggests that Modules 1-3 can be taken concomitantly does not motivate a person of skill in the art to combine Modules 1-3 of Riley into a single composition as the Examiner suggests since this would ignore the teachings at col. 10, lines 46-51 of Riley that the Modules were specially formulated to provide flexibility in when and what compositions are taken, and to take into consideration vitamin-vitamin interactions and vitamin-mineral interactions. A skilled person, realizing this, would be motivated to formulate Modules 1-3 separately, as was done by Riley, to avoid potential vitamin-vitamin and vitamin-mineral interactions which could occur if all of the ingredients were mixed together in a single

composition as the Examiner suggests, and to retain the flexibility of being able to dose Modules 1-3 either together or separately.

For these reasons, this new position by the Examiner is incorrect and should be disregarded.

II. Second New Issue

In the Examiner's Answer, the Examiner, for the first time, took the position that,

Appellant argues that the Skilled Artisan would not mix the ingredients from different modules of Riley, because Riley is concerned with vitamin-vitamin and vitamin-mineral interactions. Appellant cites col. 10, lines 46-51. Note that in col. 10, Riley merely states the considerations for designing its particular modules. Also note that Riley specifically teaches many add-on formulations that can be taken with Module 1: 'The add-on modules of the formulation allow the Module 1 AM/PM formula, Module 2, one of the variations of Module 3 and Module 4, to be taken as may be indicated.' Col. 8, lines 15-18 [of Riley].

Given these particular teachings of Riley, the Skilled artisan would indeed be motivated to combine the different modular formulations of Riley.

See Examiner's Answer pages 5-6. First, the Examiner does not explain why the indication in Riley that Modules 2-4 are "add-on" modules suggests to a person of skill in the art to combine the modular formulations into a single composition. Thus, the Examiner's reasoning fails on this point.

Second, it appears that this portion of Riley supports the Appellant's position since Riley has specifically formulated Modules 1-3 as separate, distinct compositions, providing valid reasons for doing so. Specifically, the modular form of Riley's compositions provides flexibility to choose which modules are to be taken, as well as when to take each module. Thus, combining the modules of Riley as suggested by the Examiner, would eliminate this advantage, since then all ingredients would have to be taken together at the same time.

Also, combining Modules 1-3 of Riley would be expected to lead to undesirable vitamin-vitamin and/or vitamin-mineral interactions and thus the skilled person would avoid formulating the Modules of Riley together as a single composition for this additional reason. See col. 10,

lines 46-51 of Riley.

Finally, the Examiner appears to be taking the position that the Board should ignore the statement at col. 10, lines 46-51 of Riley on the basis that this is merely a statement of the considerations in designing Riley's modules. This position is legally incorrect since, as the Examiner correctly points out later in the Examiner's answer, the whole contents of the Riley reference must be considered. Moreover, the reasons why Riley formulated Modules 1-3 separately, as enumerated at col. 10, lines 46-51 of Riley, are the most relevant disclosure of Riley in relation to the issue of whether a skilled person, reading Riley, would combine Modules 1-3 into a single composition. Thus, these "mere considerations" as the Examiner characterizes them, are actually the most important disclosure of Riley since these considerations explain that there are several advantages to formulating Modules 1-3 as separate compositions, rather than as a single composition. The attainment of these several advantages would be sufficient motivation for a skilled person to insist on formulating Modules 1-3 separately rather than to combine them as the Examiner suggests.

Accordingly, the Examiner's second new argument is incorrect and/or unsupported by the facts for these reasons and thus should be disregarded.

III. Third New Issue

The Examiner, for the first time in the Examiner's Answer, criticizes the Appellant for relying on the teachings of claim 2 of Riley when enumerating the differences between the teachings of Riley and the claimed invention. This criticism is misplaced since it was the Examiner that relied on the teachings of claim 2 of Riley as the basis of the rejection under 35 U.S.C. §103(a). The first sentence in support of the Examiner's rejection at issue in this appeal reads as follows:

Riley (US 5,976,568) discloses an oral daily supplement composition comprising Vitamins A, D, E, C (Buffered Calcium Ascorbate, Ascorbic Acid and Ascorbyl Palmitate) and quercetin, see claim 2. (emphasis added).

In the Examiner's Answer, the Examiner states,

The appellant lists the differences between Riley and the instant claims. In enumerating these differences appellant relies on the teachings of a single claim in Riley. Note that the teachings of the reference are not limited to claim 2. The reference should be taken as a whole and all of its teachings considered.

Examiner's Answer, page 6, section (11), part B. As noted above, the appellant relied on claim 2 of Riley as the starting point for the obviousness analysis because the Examiner relied on claim 2 of Riley in support of the rejection.

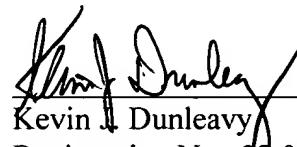
While the appellant agrees with the Examiner's statement that the reference must be considered as a whole, it is notable that the Examiner is now shifting the basis of the initial rejection from being based on claim 2 of Riley to being based on a combination of Modules 1-3 as exemplified on in Tables II-III of Riley. This shift in the Examiner's position demonstrates that the Examiner does not consider the original reasoning offered in support of the rejection at issue in this appeal to be sufficient, and, as a result, the Examiner has now shifted to a new line of reasoning in support of the rejection.

The new line of reasoning offered by the Examiner, namely, that the skilled person would combine Modules 1-3 of Tables II and III of Riley into a single composition, directly contradicts the teachings of Riley to formulate these modules as separate compositions, as discussed above, in order to obtain flexibility as to what modules are to be taken and when they are to be taken, and in order to avoid vitamin-vitamin and vitamin-mineral interactions. Accordingly, this new line of reasoning is contrary to the teachings of Riley and thus should be disregarded.

IV. Conclusion

For the foregoing reasons, and the reasons given in the Appeal Brief, appellant respectfully submits that the sole remaining rejection should be reversed, and all claims allowed, and such a decision is respectfully solicited.

Respectfully submitted,


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Date: August 4, 2003
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